REMARKS

Claims 34-39 and 46-94 are pending, claims 35 and 46-94 are withdrawn from consideration and claims 34 and 36-39 stand rejected.

Priority

The Applicant submits that the present application is entitled to claim priority to U.S. Application No. 08/625,328, filed April 1, 1996, U.S. Application No. 08/710,802, filed September 23, 1996 and U.S. Application No. 08/828,683, filed March 31, 1997, for common subject matter originally disclosed in these earlier applications.

Information Disclosure Statement

In the event that the present application issues as a patent, the Applicant hereby provides permission to the Examiner to update the previously filed 1449 form to add publication dates, as requested.

Rejections Under 35 U.S.C. § 112, 1st Paragraph

Claim 34 stands rejected under 35 U.S.C. § 112, 1st paragraph, as purportedly not supported by the specification and claims. In particular, the Examiner indicates that "an isolated nucleic acid encoding Apo-3 polypeptide comprising amino acid residues 25-417 has no clear support in the specification and the claims as originally filed." December 14, 2004 Office Action, page 4.

As previously indicated, amino acid residues 1-24 of SEQ ID NO:6 comprise a signal sequence. As described in the specification, amino acid residues 25-417 of SEQ ID NO:6 comprise an extracellular domain, transmembrane domain and intracellular domain. *See, e.g.*, the specification at page 20, lines 8-11. Secreted forms of the Apo-3 polypeptide are contemplated and encompassed by the present claims. *See, e.g.*, the specification at page 13, lines 20-24. Cleavage of the Apo-3 signal sequence after secretion yields a polypeptide having amino acid residues 25-417 of SEQ ID NO:6. Moreover, the Applicant respectfully directs the Examiner's attention to the specification at page 23, line 6-31, wherein the signal sequence component is discussed. Heterologous signal sequences incorporating a specific cleavage site at the N-terminus of the mature protein, which are subsequently cleaved

(yielding a polypeptide having amino acid residues 25-417 of SEQ ID NO:6) are described. *See, e.g.*, the specification at page 23, lines 13-15.

Accordingly, an isolated nucleic acid encoding Apo-3 polypeptide comprising amino acid residues 25-417 of SEQ ID NO:6 is adequately described in the present specification.

Rejections Under 35 U.S.C. § 102(e)

Claims 34 and 36-39 stand rejected under 35 U.S.C. § 102(e) as purportedly anticipated by U.S. Patent No. 6,153,402 (Yu *et al.*).

The Applicant maintains the position that Yu *et al.* does not have effective 102(e) prior art status against the present application since it fails to satisfy the requirements of Section 112 or Section 101 required for an effective priority claim to the Application filed March 12, 1996. *See* Applicant's Amendment (in connection with the present application), mailed April 7, 2004, pages 15-16. As such, Yu *et al.* does not anticipate the present claims.

Moreover, it is pointed out that neither the Yu *et al.* patent nor any of its priority applications teach the specifically claimed species of DNA encoding the Apo-3 polypeptide regions of the present claims. In particular, Yu *et al.* fails to provide any direction which would reasonably lead persons skilled in the art to the particular subgenus comprising these polypeptide regions (*i.e.*, amino acid residues 1-417, amino acid residues 25-198 (extracellular domain), 25-417 (extracellular domain, transmembrane domain and intracellular domain) or 338-417 (death domain) of SEQ ID NO:6). A mere reference to the entire sequence without any blazemarks leading one of skill in the art to the specifically recited species of DNA encoding the recited regions, which have clearly defined boundaries, versus any other regions of the polypeptide clearly does not elucidate the specific regions of the present claims. *See In re Arkley*, 172 USPQ 524 (CCPA 1972) ("[F]or the instant rejection under 35 USC 102(e) to have been proper, the . . . reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.").[1]

[1] *See also Fujikawa v. Wattanasin*, 39 USPQ2d 1895, 1904-05 (Fed. Cir. 1996) (indicating that although *ipsis verbis* disclosure is not necessary to satisfy the written description requirement, the application must provide adequate direction which would reasonably lead persons skilled in the art to a particular subgenus - "it is easy to bypass a tree in the forest, even one that lies close to the trail, unless the point at which one must leave the trail

To the extent that Yu *et al.* provides any direction to a signal peptide, extracellular, transmembrane, intracellular or death domain in the March 12, 1996 application, it points to completely different domains having different boundaries within its longer 428 amino acid DR3-V1 (DDCR) polypeptide versus the polypeptide of the present claims. *See* Application No. 60/013,285 at page 7, line 34-page 8, line 3; page 11, lines 10-19; Figure 1; SEQ ID NO:1.[2] With regard to Yu et al's DR3 polypeptide, as discussed above, this polypeptide was initially disclosed in the second priority application, after the September 23, 1996 priority date of the present invention. Moreover, similar to the first priority application and the DDCR polypeptide, this later disclosure describes DR3 having different domains with different boundaries (*e.g.*, the extracellular, transmembrane and death domains) versus a polypeptide of the present claims. *See* Application No. 60/028,711 at page 6, lines 15-19; page 31, lines 18-29; Figure 1; SEQ ID NO:2. Accordingly, the Yu reference is not an effective anticipatory reference under 102(e) as its priority applications do not describe, in a manner sufficient under Section 112, the currently claimed polypeptide. *See, e.g., In re Wertheim and Mishkin*, 209 USPQ 554 (CCPA 1981).

By the current written description standard, and, in fact, by the standard applied to the present claims by the Examiner with regard to the 25-417 region discussed above (*see* December 14, 2004 Office Action, page 4), Yu *et al.* clearly fails to describe the limitations of the pending claims.

For all these reasons, Yu *et al.* fails to anticipate the pending claims. It is requested that the Section 102(e) rejection of the pending claims be withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicant considers this application to be in condition for allowance, and request the prompt issuance of a Notice of Allowance.

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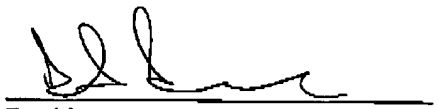
to find the tree is well marked." 39 USPQ2d at 1905.); *Suntiger, Inc. v. Blublocker*, 51 USPQ2d 1811, 1818 (Fed. Cir. 1999) ("The case law makes clear that disclosure of a generic expression encompassing a large number of possible variants is not a description of all of them." *Id.* (citing *In re Ruschig*, 154 USPQ 122 (CCPA 1967) and *Fujikawa*).

[2] The Applicant points out that the domains of DR3-V1 (DDCR) set forth in Yu *et al.* (U.S. Patent No. 6,153,402) are not those set forth for DDCR in Yu *et al's* first priority application. *Compare* Application No. 60/013,285 at page 7, line 34-page 8, line 3; page 11, lines 10-19 with U.S. Patent No. 6, 153,402 at col. 4, lines 25-31. All of these domains were changed (without explanation) between the first and second Yu *et al.* priority applications. *See id.*; *see also* Application No. 60/028,711 at page 6, lines 15-19.

Docket No. 22338-1207 U.S. Patent Application No. 09/993,234

In the unlikely event that the Patent Office determines that extensions and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or fees due to our Deposit Account No. **18-1260**, referencing Docket No. **22338-1207**. Any refund should be credited to the same account. The Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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